K062908

510(k) Summary
OrthoPro Hemi Toe

Date September 25, 2006

NOV 13 2006

Submitter

OrthoPro LLC
3450 Highland Dr.
#303
Salt Lake City, UT 84106

Contact person

J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Trade Name OrthoPro Hemi toe

Common name Hemi toe

Classification name prosthesis, toe, hemi-, phalangeal
Class II per 21 CFR section 888.3730

Product Code KWD

Equivalent Device
Futura Biomedical Metal Hemi Toe Implant (K971047)
Kinetikos Medical K2 Hemi Toe Implant System (K023770)
Townley Great Toe Joint (K911378)

Device Description

The Ortho/Pro Hemi Toe is a single stemmed resurfacing prosthesis for the first proximal phalanx designed to supplement first metatarsal phalangeal joint arthroplasty. The concave congruent articular surface has a mirror finish to minimize friction and matches the adjacent metatarsal head. The oval shape helps to reduce impingement on the metatarsal head, maintain range of motion and reduce pain without altering the joint biomechanics. The Hemi Toe requires minimal bone resection and provides full range of motion of the first metatarsophalangeal joint (MPJ).

Intended Use

The Ortho/Pro Hemi Toe is a single stemmed resurfacing prosthesis for the first proximal phalanx designed to supplement first metatarsal phalangeal joint arthroplasty. Indications include hallux limitus or hallux rigidius, painful hallux valgus, revision of failed previous surgery and painful arthritis.

Summary Nonclinical Tests

The Ortho/Pro Hemi Toe does not incorporate any new technological characteristics as compared to the predicate devices. The Ortho/Pro Hemi Toe and the predicate devices are made from the same material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OrthoPro LLC
% Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

NOV 1 3 2006

Re: K062908
Trade/Device Name: Ortho/Pro Hemi Toe
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis.
Regulatory Class: II
Product Code: KWD
Dated: September 25, 2006
Received: September 27, 2006

Dear Mr Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062908

Device Name: Ortho/Pro Hemi Toe

Indications for Use:

The Ortho/Pro Hemi Toe is designed to supplement first metatarsal phalangeal joint arthroplasty. Indications include hallux limitus or hallux rigidius, painful hallux valgus, revision of failed previous surgery and painful arthritis.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062908